

The specification has been carefully reviewed and editorial changes have been effected. All of the changes are minor in nature and therefore do not require extensive discussion. Specifically, the specification headings have been amended in conformance with U.S. practice.

Claims 1, 3-9 and 11-20 have been cancelled without prejudice and replaced with new claims 21-40. New claims 21-38 correspond essentially to original claims 1, 3-9 and 11-20 respectively. Further, new claims 39 and 40 have been presented to further protect specific embodiment of the present invention. Support for the new claims is readily apparent from the teachings of the specification and the original claims. More particularly, support can be found on pages 11, 12 and 14 and the Examples of the specification.

With regard to the objection of the amendments filed on April 5, 1999 and September 13, 1999 under 35 U.S.C. 132 for introducing new matter, Applicants believe that the Examiner is mistaken in this regard and that this objection should be withdrawn.

Under U.S. practice, matter not found in either the drawings or specification of an original application, involving a departure from or an addition to the original disclosure constitute new matter and therefore cannot be added to (or deleted from) the specification. Further, it is also important to note that new matter should be evaluated in light of the claims since new matter can only be subject matter which has been introduced into the disclosure to properly support the claimed subject matter.

The Preliminary Amendments filed on April 5, 1999 and September 13, 1999 deleted the contents relating to anticancer from the specification. This deletion does not involve a "departure from the original disclosure" since the original and current claims are directed to an apoptosis-

inducing agent or food or beverage having apoptosis inducing activity. Please note that the claims directed to an anticancer agent have been cancelled without prejudice and thus, subject matter which support such claims are no longer necessary to the disclosure. As a result, the deleted subject matter relating to anticancer should not constitute new matter under U.S. practice.

Further, the same Preliminary Amendments also limited the glycerolipid and/or glyceroglycolipid of the present invention to “the glycerolipid and/or glyceroglycolipid being free from phosphate ester and phosphonate ester in molecular structure”. Although the phrase “glycerolipid and/or glyceroglycolipid being free from phosphate ester and phosphonate ester in molecular structure” is not expressly disclosed in the specification, the subject matter described by the phrase is clearly supported by the teachings of the specification.

The limitations “glycerolipid and/or glyceroglycolipid being free from phosphate ester and phosphonate ester in molecular structure” are based on the Examples of the specification. In the Examples, it is mentioned that in every case where mass spectrum analysis is conducted of the substance having apoptosis inducing activity, fatty acid, sugar, and glycerol are detected. In other words, it is clearly disclosed in the specification that the apoptosis inducing agent of the present invention is “the glycerolipid and/or glyceroglycolipid being free from the phosphate ester and phosphonate ester in molecular structure”.

Applicants also wish to note that the terms “glycerolipid and/or glyceroglycolipid” have meanings which exclude a substance containing phosphate ester and phosphonate ester in molecular structure (i.e. glycerophospholipid). In other words, since the present invention has been accomplished based on the knowledge that glycerolipid consisting of fatty acid and glycerol

and/or glyceroglycolipid consisting of fatty acid, sugar and glycerol show an apoptosis inducing activity, the present inventors clearly did not intend to include “glycerophospholipid” (substance containing phosphate ester and phosphonate ester in molecular structure) in the present invention. It is for this purpose that the present inventors use the specific term “the glycerolipid” and/or glyceroglycolipid” to describe the apoptosis inducing agent of the present invention.

Thus, in light of the above, Applicants respectfully submit that the new matter objection of the amendments under 35 U.S.C. 132 cannot be sustained and should be withdrawn.

With regard to the rejection of claims 1, 3-9 and 11-20 under 35 U.S.C § 112, first paragraph, this rejection also cannot be sustained for the same reasons as noted above and should be withdrawn. As stated earlier, the phrase “glycerolipid and/or glyceroglycolipid being free from the phosphate ester and phosphonate ester in molecular structure” is clearly supported by the Examples disclosed in the present specification. Further, the terms “glycerolipid and/or glyceroglycolipid” should not be interpreted to include phosphate ester and phosphonate ester since such terms do not encompass “glycerophospholipid”. Thus, Applicants again respectfully request that withdraw of this rejection in view of the above remarks.

With regard to the rejection of claims 3-8 under 35 U.S.C § 112, second paragraph, this rejection has been overcome in view of the wording of the new claims and thus, should be withdrawn.

With regard to the rejection of claim 1 under 35 USC § 102(b) as being anticipated by Nojima et al. or Yazawa et al, this rejection is deemed to be untenable and is thus respectfully traversed.

To constitute anticipation of the claimed invention, a single prior art reference must disclose each and every material element of the claim. Here, in this case, Nojima et al. only discloses an antitumor agent containing a glyceroglycolipid. In addition, Yazawa et al. only discloses a carcinogenic promoter inhibitor using glyceroglycolipid as an active component. Yazawa et al. state that the carcinogenic promoter inhibitor has an inhibiting action to carcinogenic promotion, i.e. carcinogenic process of normal cells.

Conversely, the present invention is directed to an agent which induces apoptosis programmed in cells. Apoptosis is a phenomenon which does not always occur in cancer cells but generally occurs in common cells.

Thus, since the present invention and the cited references are based on completely different concepts, the cited references do not anticipate the present invention and the rejection of the claim under 35 USC § 102(b) should be withdrawn.

With regard to the rejection of claims 1, 3-5, 7-8 and 17-18 under USC § 102(e) as being clearly anticipated by Winget (U.S.P. 5,767,095), this rejection will be overcome by the filing of the verified translation of the certified priority document. Applicants submit that since Applicants' priority date of November 8, 1996 is prior to the filing date, January 7, 1997, of Winget, the Winget reference is no longer valid as a prior art reference. Thus, this rejection should be withdrawn upon receipt of the verified translation of the certified priority document.

With regard to the rejection of claims 6, 11-16, and 19-20 under 35 USC § 103(a) as being unpatentable over both Winget and Yazawa et al. in view of Wright et al and Nelson, this rejection will also be overcome by the filing of the verified translation of the certified priority

document. Since as stated earlier, Winget will no longer be a valid prior art reference after the filing of the verified translation, this rejection should also be withdrawn upon the receipt thereof.

In view of the foregoing amendments and remarks, it is respectfully submitted that the Application will be in condition for allowance pending the filing of the verified translation of the certified priority document. The Examiner is respectfully request to await the filing of the translation and delay any future action until the translation is received, if possible.

Otherwise, if the Examiner has any suggestions for expediting allowance of the application or believes that direct communication with Applicant'(s)' attorney will advance the prosecution of this case, the Examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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